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Registration Decision

RD2014-09

Garlic Juice

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Registration Decision for Garlic Juice

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of U C Garlic Juice (technical grade active ingredient) and Mosquito Barrier (end-use product), containing the technical grade active ingredient garlic juice, to repel mosquitoes in outdoor environments.

These products were first proposed for registration in the consultation document¹ Proposed Registration Decision PRD2013-18, *Garlic Juice*. This Registration Decision² describes this stage of the PMRA's regulatory process for PRD2013-18 and summarizes the Agency's decision. No comments were received during the consultation process. This decision is consistent with the proposed registration decision stated in PRD2013-18.

For more details on the information presented in this Registration Decision, please refer to PRD2013-18, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable³ if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value⁴ when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

³ "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

⁴ "Value" as defined by subsection 2(1) of *Pest Control Products Act*: "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

What Is Garlic Juice?

Garlic juice is an extract of garlic (*Allium sativum* var. *sativum*). It is the active ingredient in the end-use product Mosquito Barrier. Various diallyl sulfide compounds, which are among the main components of garlic juice, are repellent to mosquitoes.

Health Considerations

Can Approved Uses of Garlic Juice Affect Human Health?

Garlic juice is unlikely to affect your health when used according to label directions.

Exposure to garlic juice may occur when handling and applying the product, Mosquito Barrier, as well as during typical residential activities following application. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient, garlic juice, is of low acute toxicity by the oral and dermal routes, may be a skin and eye irritant, and a possible dermal sensitizer. Because garlic is a known mucosal irritant, inhalation of garlic juice mist or vapour may result in throat and respiratory tract irritation. The end-use product, Mosquito Barrier, is of low acute toxicity by both the oral and dermal route, may be a skin and eye irritant, and a possible dermal sensitizer. Cautionary statements alerting the user to garlic juice's acute toxicity, potential as a skin and eye irritant, and dermal sensitizer are required on the technical grade active ingredient product label, as well as Mosquito Barrier being a possible skin and eye irritant, and a dermal sensitizer.

Inhalation, dermal, and ocular exposures are possible when applying the product, particularly to the applicator and bystanders located near the treatment area. Also, entry into a recently sprayed area may result in dermal exposure. Therefore, spray advisory and restricted-entry statements are required on the end-use product label to minimize applicator and bystander exposures.

The data requirements for short-term toxicity, prenatal developmental toxicity, and genotoxicity were not required by the PMRA based on the long history of safe consumption of garlic as a whole foodstuff and garlic juice in natural health products.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The use pattern of Mosquito Barrier is for non-food situations. Garlic readily degrades in the environment, so any inadvertent exposure of garlic juice to food, feed, or water from drift or direct contact is not expected to result in any dietary risk.

Occupational Risks From Handling Garlic Juice

Occupational Risks are not of concern when garlic juice is used according to label directions, which include protective measures.

Domestic users mixing, handling and applying Mosquito Barrier to areas that attract mosquitoes, such as plants, shrubs, turf, and under decks and porches, can come into direct contact with garlic juice on the skin and in the eyes. Following the precautionary label statements aimed at minimizing exposure to the product will ensure domestic users are appropriately protected. Potential for inhalation of garlic juice while handling and applying the product is anticipated to be negligible if users observe the precautionary label statements.

Accidental bystander exposure is possible from spray drift, but exposure is expected to be negligible if the precautionary label statements are observed by the applicator.

Postapplication exposure is possible in individuals who immediately enter freshly treated areas. The transfer of garlic juice from turf or foliar application to an individual who is not sensitive to garlic will not pose a health concern.

Value Considerations

What Is the Value of Mosquito Barrier?

Mosquito Barrier is an area repellent that can reduce nuisance levels of mosquitoes.

Diluted in water to a concentration of 3–6%, Mosquito Barrier is applied as a broadcast spray to vegetation and other substrates to repel mosquitoes from the area.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Mosquito Barrier to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

The statements, “MAY BE A SKIN AND EYE IRRITANT” and “POTENTIAL SKIN SENSITIZER” have been included on the principal display panel of the general label and “Do not swallow,” “Avoid getting on skin and in eyes,” “May cause skin and eye irritation,” “Avoid inhaling/breathing mist or vapours,” and “Potential skin sensitizer” have been included in the PRECAUTIONS section of the secondary display panel of the end-use product label.

Because some individuals may be sensitive to garlic the statements, "Apply only when the potential for drift is minimal," "Individuals who are sensitive or allergic to garlic should avoid handling Mosquito Barrier" and "Individuals who are sensitive or allergic to garlic should avoid treated areas until dry or until after a heavy rain" have also been included in the PRECAUTIONS section of the secondary display panel of the general label.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2013-18) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection⁵ regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service.

⁵ As per subsection 35(1) of the *Pest Control Products Act*.